

IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA  
CLARKSBURG DIVISION

**FILED**

JUN 28 2002

U.S. DISTRICT COURT  
CLARKSBURG, WV 26301

MYLAN PHARMACEUTICALS INC.,

Plaintiff,

v.

No. 1:02 CV 88

AMERICAN SAFETY RAZOR COMPANY;  
MEGAS BEAUTY CARE, INC., D/B/A  
PERSONNA MEDICAL; BBA U.S.  
HOLDINGS, INC.; BBA NONWOVENS  
SIMPSONVILLE, INC.; AND  
INTERNATIONAL PAPER COMPANY,  
INDIVIDUALLY AND D/B/A VERATEC,

Defendants.

JURY TRIAL DEMANDED

**AMENDED COMPLAINT**

Mylan Pharmaceuticals Inc., by and through its undersigned counsel, files the following Amended Complaint:

**I. Parties**

1. Plaintiff Mylan Pharmaceuticals Inc. ("Mylan") is a corporation organized under the laws of the state of West Virginia, with its principal place of business in West Virginia.

2. Defendant American Safety Razor Company ("American Razor") is a corporation organized under the laws of the state of Delaware, with its principal place of business located at 240 Cedar Knolls Road, Cedar Knolls, New Jersey, 07927.

3. Defendant Megas Beauty Care, Inc., d/b/a Personna Medical, is a corporation organized under the laws of the state of Delaware, with its principal place of business located at 15501 Industrial Parkway, Cleveland, Ohio, 44135.

4. At all times material hereto, Megas Beauty Care, Inc. was a division of American Razor and American Razor was doing business as Personna Medical, which had/has a principal place of business at One Razor Blade Lane, Verona, Virginia 24482 (collectively hereafter all referred to as "Personna Medical"). Based upon information and belief, Megas Beauty Care, Inc. is now a subsidiary of U.S. Cotton, LLC.

5. Defendant BBA U.S. Holdings, Inc. is a corporation organized under the laws of the state of Delaware, with a principal place of business at 401 Edgewater Place, Wakefield, Massachusetts, 01880.

6. Defendant BBA Nonwovens Simpsonville, Inc. is a corporation organized under the laws of the state of Delaware, with a principal place of business at 840 S.E. Main Street, Simpsonville, South Carolina, 29681.

7. Based upon information and belief, BBA U.S. Holdings, Inc. is the holding company for various U.S. BBA Nonwovens entities, including BBA Nonwovens Simpsonville, Inc., which is the successor to BBA Nonwovens Walpole and is the North American Hygiene/Medical Headquarters for BBA Nonwovens USA, which includes BBA Nonwovens, Griswoldville and Veratec (collectively hereafter all referred to as "BBA Nonwovens").

8. International Paper Company is a corporation organized under the laws of the state of New York, with a principal place of at 400 Atlantic Street, Stamford, Connecticut, 06921.

9. At a period of time relevant hereto, in the beginning of 1998, International Paper Company did business individually and controlled and/or did business as its nonwoven fabrics division, Veratec (collectively "International Paper").

10. Based upon information and belief, in July of 1998, International Paper sold its Veratec division to BBA Nonwovens or an affiliate.

## **II. Jurisdiction and Venue**

11. Jurisdiction in this Court is proper pursuant to 28 U.S.C. § 1332(a) because the amount in controversy exceeds \$75,000, exclusive of interest and costs, and because there is complete diversity of citizenship between plaintiff and defendants.

12. This Court is the proper venue for the action pursuant to 28 U.S.C. § 1391(a) in that the defendants regularly conduct business within this district, and a substantial part of the events giving rise to this claim occurred within this district.

## **III. Factual Background**

13. Mylan is involved in the research, development, manufacture and distribution of generic pharmaceutical products.

14. As part of its packaging operation, Mylan has included cotton as a component of its container/closure systems for solid oral dosage pharmaceutical products. Prior to April 1997, Mylan purchased cotton coils from American White Cross, Inc. ("American White Cross") for this purpose. The parties developed a course of dealings, including the requirements and specifications of the cotton to be provided to Mylan.

15. In April of 1997, American White Cross sold its fiber based product lines to Megas Beauty Care, Inc., a division of American Safety Razor. American Safety Razor's division, Personna Medical, became responsible for marketing cotton coil to American White Cross's former customers, including Mylan.

16. On April 21, 1997, Personna Medical wrote to customers of American White Cross, including Mylan, and informed them that Personna Medical was assuming the sales and

marketing responsibility for all of American White Cross's pharmaceutical cotton coil. Personna Medical represented in writing that business would continue as usual, that all management and quality control systems would remain intact, and that customers would be notified well in advance if any changes were contemplated.

17. On or about May 20, 1997, American White Cross also notified its customers, including Mylan, of this change. Specifically, American White Cross informed Mylan and others that American Razor would market coil under the name Personna Medical and would continue providing coil that conformed to the customers' requirements and was manufactured under the same controls on which the customers had come to rely. American White Cross further represented that no substantive change would be made without first consulting customers and allowing them ample time to assess the impact of any change that may be proposed.

18. Additionally, Personna Medical agreed to conform to the prior course of dealing between Mylan and American White Cross.

19. In reliance on these representations, Mylan continued to do business with Personna Medical as it had previously done with American White Cross.

20. Mylan and Personna Medical developed a course of dealings whereby Mylan would verbally order cotton from Personna Medical in accordance with its needs. Mylan would confirm each verbal order with a written purchase order. Personna Medical would then ship the requested cotton to Mylan, along with a Certificate of Analysis and invoice for each shipment.

21. Each purchase order forwarded by Mylan contained terms and conditions, including the following representations:

Seller [Personna Medical] represents that it has and will continue during the performance of this order to comply with the provision of all federal, state and local laws and regulations by reason of the violation of which liability may accrue to Buyer [Mylan]... If this

order relates to any food, drug, cosmetic, or substance the intended use of which may reasonably result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food, drug or cosmetic, including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, or transporting, Seller hereby guarantees that the articles comprising each shipment or other delivery hereafter made by Seller to Buyer, as of the date of such shipment and/or delivery, is not adulterated or misbranded within the Federal, Food, Drug, and Cosmetic Act, as amended or applicable Federal State laws and Municipal ordinances. If Buyer sustains any monetary damage or legal fees as a result of the sale or use in finished product form or otherwise, of any items delivered by Seller covered hereunder and if such liability or exposure is found to be Seller's fault, full or contributory, Seller shall be fully responsible for all such damages sustained by Buyer and/or its customers, including legal fees and expenses.

22. Based upon information and belief, since the late 1980s, Personna Medical has contracted first with International Paper and then BBA Nonwovens, to supply it with processed cotton. As part of this process, International Paper and BBA Nonwovens exposed the cotton to a bleaching process that included treating it with hydrogen peroxide.

23. At all times material hereto, Personna Medical, BBA Nonwovens and International Paper knew the cotton sold was being used for pharmaceutical purposes. Personna Medical maintained drug master files with the Food and Drug Administration ("FDA").

24. Beginning in mid-1998, International Paper, and then BBA Nonwovens, began utilizing a new process for certain customers who requested it, which included Personna Medical, whereby they added an additional hydrogen peroxide rinse that had not been previously used in the process.

25. Based upon information and belief, on or about November 5, 1998, following a customer complaint, Personna Medical began an investigation into residual hydrogen peroxide in cotton it had sold.

26. Based upon information and belief, on or about November 17, 1998, Personna Medical instructed BBA Nonwovens to return to their normal procedure for hydrogen peroxide treatment.

27. Furthermore, based upon information and belief, an additional customer complaint was received by Personna Medical regarding excess residual hydrogen peroxide. Said customer notified the FDA of its findings in February of 1999.

28. Following this notification, the FDA visited both Personna Medical and BBA Nonwovens and requested a list of customers affected by the subject cotton from Personna Medical.

29. It was only at this point in time that Personna Medical notified Mylan.

30. On or about March 2, 1999, Personna Medical wrote to its pharmaceutical cotton coil customers, including Mylan, and informed them that it had provided these customers with cotton, bleached by an outside supplier, BBA Nonwovens/Veratec. Personna Medical informed these customers that BBA Nonwovens/Veratec had changed its process during 1998 by introducing an expanded hydrogen peroxide treatment, and subsequent testing indicated that there were varying levels of residual hydrogen peroxide in the processed cotton during that time period.

31. In its March 2, 1999 letter, Personna Medical identified the specific affected lots of cotton from its U.S. production as lots numbered between 575717 and 621648, which were shipped to customers between June of 1998 and November of 1998.

32. Personna Medical specifically informed its pharmaceutical customers that if they had cotton within the above-mentioned lot numbers, they should immediately quarantine these lots and contact Personna Medical for instructions on disposition and replacement of the cotton.

33. Personna Medical further informed these customers that if the subject lot numbers had been used in production, the customers should determine if finished product specifications were being met and take appropriate corrective action if necessary.

34. Upon investigation, Mylan determined that it had purchased ten lots of cotton from Personna Medical that had undergone the additional hydrogen peroxide treatment.

35. The relevant lot numbers purchased by Mylan from Personna Medical were lot numbers: 582760; 582758; 590893; 593200; 596196; 596197; 602022; 602023; 605992; and 610042 (the "Defective Lots"). Mylan received the first of the Defective Lots on July 6, 1998 and the last was received on December 15, 1998.

36. Based upon information and belief, the Defective Lots had been supplied to Personna Medical from International Paper individually and/or its Veratec division and from BBA Nonwovens. All or some of the Defective Lots were treated at the BBA Nonwovens Griswoldville, Massachusetts facility.

37. The Defective Lots' nonconformance was not readily discoverable by Mylan upon its inspection at the time of delivery from Personna Medical or by review of the Certificates of Analysis. By the time that Personna Medical notified Mylan of the potential problem with the Defective Lots, Mylan had already used them in production.

38. Upon receipt of the notification from Personna Medical, Mylan immediately began an investigation into the Defective Lots, their exposure to Mylan's products, and the effect the exposure would have on the products.

39. Following Mylan's investigation, it determined that the cotton had adversely affected various products. Mylan analyzed its data and discussed its findings with the FDA. Based upon these factors, Mylan recalled two products, Trifluoperazine HCl Tablets and

Fluphenazine HCl Tablets, due to a failure to assure product potency. The loss of potency was caused by abnormal degradation from the excessive hydrogen peroxide levels in the cotton coil.

40. Mylan incurred significant expenses as a result of these recalls, including but not limited to, the initial notification and subsequent monthly costs associated with the recall programs and the costs related to reimbursement of customers for returned product.

41. In addition, Mylan incurred damages, in excess of \$75,000, associated with various batches of Mylan manufactured finished drug products that were deemed unacceptable for sale by Mylan quality management, due to problems caused by the products being packaged with cotton coil containing excessive hydrogen peroxide.

42. After completing its investigations, taking the necessary remedial steps, and calculating its damages, Mylan seasonably wrote to the defendants and notified them that due to the foregoing breaches and defects, Mylan expected payment for its losses.

43. Nonetheless, the defendants have refused to compensate Mylan for such damages.

**COUNT I**  
**BREACH OF EXPRESS WARRANTY**  
**(Mylan v. American Razor)**

44. Mylan hereby incorporates by reference the averments set forth in paragraphs 1 through 43 above, as though fully set forth herein.

45. Personna Medical agreed to provide cotton in compliance with certain expressly agreed upon specifications and specifications established through the parties' course of dealings.

46. Personna Medical breached express warranties it made to Mylan regarding the quality of the cotton coil it would provide to Mylan by selling Mylan cotton coils that deviated from the established specifications.



47. As a direct and proximate result of Personna Medical's breaches, Mylan has incurred damages in excess of \$75,000.

**COUNT II**  
**BREACH OF IMPLIED WARRANTIES**  
**(Mylan v. American Razor)**

48. Mylan hereby incorporates by reference the averments set forth in paragraphs 1 through 47 above, as though fully set forth herein.

49. Personna Medical impliedly warranted to Mylan that the materials and services provided would be of a merchantable quality and would be fit for the particular purpose for which Mylan required them.

50. At the time of the purchases of Personna Medical's materials and services, Personna Medical had reason to know or did know of the particular purpose for which Mylan required the materials and services, and that Mylan would be selling its products, which included the defective cotton, to the general public for pharmaceutical purposes.

51. Mylan relied upon the skill and judgment of Personna Medical to provide materials and services suitable for the particular purpose for which Mylan required such materials and services.

52. For the reasons set forth above, the materials and services were not of a merchantable quality and were not fit for the particular purpose required by Mylan.

53. Personna Medical thus breached the implied warranty of merchantability and the implied warranty of fitness for a particular purpose under West Virginia law.

54. As a direct and proximate result of Personna Medical's breaches, Mylan has incurred damages in excess of \$75,000.

**COUNT III**  
**BREACH OF IMPLIED WARRANTIES**  
**(Mylan v. BBA Nonwovens)**

55. Mylan hereby incorporates by reference the averments set forth in paragraphs 1 through 54 above, as though fully set forth herein.

56. BBA Nonwovens impliedly warranted to users of its product, including Mylan, that the materials and services provided would be of a merchantable quality and would be fit for the particular purpose for which Mylan required them.

57. At the time of the purchases of BBA Nonwovens' materials and services, BBA Nonwovens had reason to know or did know of the particular purpose for which Mylan required the materials and services, and that Mylan would be selling its products, which included the defective cotton, to the general public for pharmaceutical purposes.

58. Mylan relied upon the skill and judgment of BBA Nonwovens to provide materials and services suitable for the particular purpose for which Mylan required such materials and services.

59. For the reasons set forth above, the materials and services were not of a merchantable quality and were not fit for the particular purpose required by Mylan.

60. BBA Nonwovens thus breached the implied warranty of merchantability and the implied warranty of fitness for a particular purpose.

61. As a direct and proximate result of BBA Nonwovens' breaches, Mylan has incurred damages in excess of \$75,000.

**COUNT IV  
BREACH OF IMPLIED WARRANTIES  
(Mylan v. International Paper)**

62. Mylan hereby incorporates by reference the averments set forth in paragraphs 1 through 61 above, as though fully set forth herein.

63. International Paper impliedly warranted to users of its product, including Mylan, that the materials and services provided would be of a merchantable quality and would be fit for the particular purpose for which Mylan required them.

64. At the time of the purchases of International Paper's materials and services, International Paper had reason to know or did know of the particular purpose for which Mylan required the materials and services, and that Mylan would be selling its products, which included the defective cotton, to the general public for pharmaceutical purposes.

65. Mylan relied upon the skill and judgment of International Paper to provide materials and services suitable for the particular purpose for which Mylan required such materials and services.

66. For the reasons set forth above, the materials and services were not of a merchantable quality and were not fit for the particular purpose required by Mylan.

67. International Paper thus breached the implied warranty of merchantability and the implied warranty of fitness for a particular purpose.

68. As a direct and proximate result of International Paper's breaches, Mylan has incurred damages in excess of \$75,000.

**COUNT V  
BREACH OF CONTRACT  
(Mylan v. American Razor)**

69. Mylan hereby incorporates by reference the averments set forth in paragraphs 1 through 68 above, as though fully set forth herein.

70. Personna Medical has breached the specific terms of its contracts with Mylan, as well as additional express and implied terms of the contracts entered into between Mylan and Personna Medical by, among other things, providing adulterated cotton and failing to provide materials and services to Mylan in a workmanlike manner, in accordance with industry and FDA standards, with appropriate care and skill, and in accordance with the terms and conditions of the contracts.

71. As a direct and proximate result of Personna Medical's breach, Mylan has incurred damages in excess of \$75,000.

**PRAYER FOR RELIEF**

Wherefore, Mylan demands judgment against the Defendants as follows:

1. Awarding Mylan damages in excess of \$75,000, plus interest, costs and attorneys fees,
  - a. For expenses related to the recall of Trifluoperazine HCl Tablets and Fluphenazine HCl Tablets;
  - b. For the cost of various batches of Mylan manufactured finished drug products that were deemed unacceptable for sale by Mylan quality management;
  - c. For lost profits on the finished drug products not sold because they were deemed unacceptable for sale by Mylan quality management;

- d. For the costs associated with Mylan's analytical testing and personnel hours related to the investigation/recall.
  - e. For reimbursement to Mylan for the Defective Cotton that it purchased but was unable to use; and
  - f. For damage to Mylan's reputation; and
2. Such other *and* further relief as this Court may deem just and appropriate.

PLAINTIFF REQUESTS A JURY TRIAL

DKW LAW GROUP, P.C.

By: 

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(412) 355-2600

(412) 355-2609 (Fax)

**CERTIFICATE OF SERVICE**

I hereby certify that a true and correct copy of the within AMENDED COMPLAINT has been served upon the following by United States First-Class Mail, postage prepaid at the following addresses:

David B. Thomas, Esquire  
Allen Guthrie & McHugh  
1300 Bank One Center  
707 Virginia Street, East  
Charleston, WV 25301

BBA U.S. Holdings, Inc.  
c/o CT Corporation System  
101 Federal Street  
Boston, MA 02110

BBA U.S. Holdings, Inc.  
401 Edgewater Place  
Wakefield, MA 01880

BBA Nonwovens  
Simpsonville, Inc.  
c/o CT Corporation System  
101 Federal Street  
Boston, MA 02110

BBA Nonwovens Simpsonville,  
Inc.  
840 S.E. Main Street  
Simpsonville, SC 29681

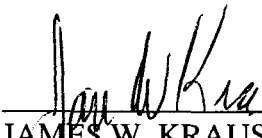
Megas Beauty Care, Inc.  
d/b/a Personna Medical  
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1300 E. Ninth Street  
Cleveland, OH 44114

Megas Beauty Care, Inc.  
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Cleveland, OH 44135

DKW LAW GROUP, PC

Dated: \_\_\_\_\_

6/27/02

  
\_\_\_\_\_  
JAMES W. KRAUS, ESQUIRE